UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE OCULAR THERAPEUTIX, INC. SECURITIES LITIGATION This Document Relates To: All Actions	Case No. 1:17-cv-12288-GAO **ORAL ARGUMENT REQUESTED** Leave to File Excess Pages Granted on July 2, 2018

REPLY MEMORANDUM IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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Plaintiffs' Opposition ("Opp.") (Dkt. No. 69) underscores the fundamental problem with the Consolidated Amended Class Action Complaint: Plaintiffs offer no contemporaneous facts establishing that, at the time of the challenged statements, Ocular's efforts to address the FDA's inspectional observations and obtain FDA approval were doomed to fail. Nothing in the Opposition overcomes the conspicuous absence of any internal document, report, or communication demonstrating even disagreement about the prospects for resolving the FDA's observations, much less that any Defendant knew that Ocular would not be able to do so in a timely manner. Instead, Plaintiffs resort to offering their own characterizations of Ocular's statements and ignoring key disclosures that Ocular *did* make. For example, while Plaintiffs suggest that Ocular "omitted the most critical problems" and "downplayed the inspection results" when it disclosed the May 2017 Form 483 (Opp. at 8), they ignore that Ocular *did* disclose what Plaintiffs refer to as the "bombshell finding" regarding particulate matter *on the very same day*. Defendants' Opening Memorandum of Law ("Mem.") (Dkt. No. 67) at 10 & Ex. D at 7.[1]

In addition to Plaintiffs' failure to allege particularized facts as required by Rule 9(b) and the PSLRA, the Court should also dismiss the Complaint for other reasons. First, Ocular issued explicit, thorough warnings about the uncertainty of FDA approval, and specifically warned that adequate resolution of the FDA's inspectional observations is a prerequisite to that approval. The Opposition's attempt to paint these cautions as "generic" cannot be squared with the Company's meaningful and specific cautionary language. Second, the challenged statements relating to Ocular's *expectations* are forward-looking and are thus protected by the Safe Harbor of the PSLRA. *See* 15 U.S.C. § 78u-5. Third, these statements of expectations also are typical expressions of opinion and optimism that are inactionable as a matter of law. Fourth, the meager

[1] Unless otherwise specified, citations to "Ex." refer to the exhibits referenced in the Declaration of Peter J. Kolovos filed with Defendants' opening memorandum. Dkt. No. 68.

facts that Plaintiffs cobble together fail to plead the required "strong inference" of scienter. At bottom, the Opposition confirms that this action is nothing more than an attempt to concoct a fraud claim out of Ocular's cautious optimism, but without any contemporaneous facts showing that any statement was false when made. For these and the other reasons set forth below and in Defendants' opening memorandum, the Court should dismiss the Complaint with prejudice.

I. PLAINTIFFS DO NOT SUFFICIENTLY ALLEGE A FALSE STATEMENT OR OMISSION

Despite the Opposition's attempt to water down the pleading standard (*see* Opp. at 9-10), Plaintiffs are required to plead a factual basis for their allegations, not conclusory assertions. *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 193-94 (1st Cir. 1999) ("plaintiff must not only allege the time, place, and content of the alleged misrepresentations with specificity, but also the factual allegations that would support a reasonable inference that adverse circumstances existed . . . ." (internal quotation marks omitted)); *In re Vertex Pharm. Inc. Sec. Litig.*, 357 F. Supp. 2d 343, 350-51 (D. Mass. 2005) (where "[p]laintiffs provide no facts to support their allegation that [defendants'] statements . . . are misleading," their claims "fail the PSLRA pleading requirements"). The Opposition fails to point to any well-pleaded facts to sustain any of Plaintiffs' three claims: (1) that the Company's statements regarding compliance with current good manufacturing practices ("cGMP") were false; (2) that Dr. Sawhney's statements during the November 9, 2016 earnings call misrepresented Ocular's progress in addressing the manufacturing issues the FDA identified in the February 2016 Form 483; and (3) that the Defendants' statements during the May 5, 2017 earnings call similarly misrepresented Ocular's progress and prospects for FDA approval.

A. The Challenged cGMP Statements Are Not Actionable

1. Plaintiffs Have Not Adequately Pleaded That The Challenged cGMP Statements Are False

As Defendants demonstrate in their opening brief (Mem. at 7-11), the Complaint provides no contemporaneous facts (let alone any pleaded with particularity) showing that Ocular's drug manufacturing practices were not cGMP complaint when Ocular made the challenged March 2016 and March 2017 cGMP statements. Unable to rectify this deficiency, Plaintiffs rely on the mere issuance of the Form 483s to argue that the cGMP statements were false and misleading. *See* Opp. at 1-2, 11-12. While Plaintiffs concede that Form 483s are not final FDA determinations (Mem. at 8; Opp. at 13), they nonetheless argue that the Form 483s establish falsity given the inspectional observations allegedly set out therein. Opp. at 13. However, given that courts have found the issuance of Form 483s insufficient to establish non-compliance with FDA regulations, it necessarily follows that the observations in those Form 483s also fail to do so—those observations also "are necessarily interim statements, subject to revision." *In re Genzyme Corp.*, No. CIV. 09-11299-GAO, 2012 WL 1076124, at *10 (D. Mass. Mar. 30, 2012);[2] *see also City of Pontiac Gen. Emps.' Ret. Sys. v. Stryker Corp.*, 865 F. Supp. 2d 811, 825 (W.D. Mich. 2012) (Form 483 did not render statement regarding compliance with FDA regulations false because "the FDA does not consider observations contained in a Form 483 as a final agency determination of noncompliance. The Form 483 thus [is] not the final word on whether the . . . facility was in compliance with FDA regulations."); *McGuire v. Dendreon Corp.*, No. C07-800MJP, 2008 WL 1791381, at *7 (W.D. Wash. Apr. 18, 2008) ("Plaintiffs

[2] As this Court noted in *Genzyme*, the FDA Form 483 itself states (on the first page) that the "inspectional observations … do not represent a final Agency determination regarding your compliance." *In re Genzyme*, 2012 WL 1076124, at *10; *see also* Mem. Ex. E; Kolovos Reply Decl. Ex. A.

inappropriately conflate the . . . issuance of a Form 483 with a finding of non-compliance . . . because the Form 483 is not a final agency determination of non-compliance.").

In any event, Plaintiffs do not dispute that Ocular disclosed both Form 483s in a timely manner (Mem. at 9-10), and indeed disclosed the February 2016 Form 483 in the very same SEC filing as the challenged March 2016 cGMP statement. *See id.* at 8. As noted in the opening brief (*id.*), it strains logic to suggest that the Form 483s somehow render the cGMP statements misleading where Ocular disclosed that the FDA had issued those Form 483s and that they included observations focused on manufacturing issues. Plaintiffs can offer no response.

Plaintiffs also argue that the July 2016 Complete Response Letter ("CRL") purportedly "confirm[ed] Ocular was never in cGMP compliance at any point after receiving the February 2016 Form 483" and thus renders false the earlier March 2016 cGMP statement. Opp. at 11 (emphasis omitted). But this is classic fraud by hindsight and cannot support a claim. Mem. at 9; *see Ezra Charitable Tr. v. Tyco Int'l, Ltd.*, 466 F.3d 1, 6 (1st Cir. 2006) ("Pleading 'fraud by hindsight,' essentially making general allegations 'that defendants knew earlier what later turned out badly,' is not sufficient." (citation omitted)); *In re Sonus Networks, Inc. Sec. Litig.*, No. 04-10294-DPW, 2006 WL 1308165, at *17 (D. Mass. May 10, 2006) (refusing to "draw the impermissible 'fraud-by-hindsight' inference, which proceeds on "the assumption that the defendants must have known of the severity of their problems earlier because conditions became so bad later on" (quoting *Serabian v. Anoskeag Bank Shares, Inc.*, 24 F.3d 357, 367 (1st Cir. 1994))).[3]

[3] Even if, as Plaintiffs suggest, the CRL was consistent with the Form 483 inspectional observations (*see* Opp. at 12 n.7), that does not change the provisional nature of the February 2016 observations, Ocular's timely disclosure of those observations, and the hindsight character of Plaintiffs' reliance on the July 2016 FDA action. *See City of Pontiac Gen. Emps.' Ret. Sys.*, 865 F. Supp. 2d at 825; *McGuire*, 2008 WL 1791381, at *7.

Plaintiffs next argue that the July 2016 CRL renders false the March ***2017*** cGMP statement (Opp. at 14), but this contention rests on the flawed theory, repeated at several points in the Opposition (*e.g.*, *id.* at 5, 14, 18, 20, 30), that the inspectional observations from the February 2016 Form 483 carried over into the May 2017 Form 483. But as Defendants have explained, the FDA communicated to Ocular in August 2016 that the Company's corrective actions as of that date "appear to address" all but one of the ten February 2016 inspectional observations. Mem. at 14 & Ex. C at 1.[4] In response, Plaintiffs offer their own unsupported and speculative analysis of how the issues in the February 2016 Form 483 might have contributed to the particulate issue that the FDA identified in the May 2017 Form 483. Opp. at 4-5. However, the February 2016 Form 483 does not mention particulates at all and does not support Plaintiffs' attempted characterizations. *See* Kolovos Reply Decl. Ex. A. What is missing, in short, are any *facts* connecting the February 2016 Form 483 observations with the particulate issue identified for the first time in the May 2017 Form 483.[5]

[4] The sole exception "relate[d] to the proposed process for identity testing of an incoming inert gas component used in the DEXTENZA manufacturing process," which is not an issue raised in the May 2017 Form 483. *See* Mem. Ex. C at 1.

[5] Plaintiffs speculate that the resolution of certain observations in the 2016 Form 483 "would likely have prevented future contamination issues" and was "necessary in order to reduce the occurrence of defects such as particulate in the drug product." Opp. at 4-5. Such conclusory assertions, which Plaintiffs do not even attempt to support with any well-pleaded allegations, internal documents, or scientific literature, are plainly insufficient to state a claim for securities fraud. *See Kader v. Sarepta Therapeutics Inc.*, No. 1:14-cv-14318-ADB, 2016 WL 1337256, at *14 (D. Mass. Apr. 5, 2016) (rejecting as speculative allegation that FDA had informed defendants that it had insufficient data to support filing of NDA where complaint contained no facts directly supporting this contention and "timing, diction, and tone" of FDA statements did not support inference); *Driscoll v. Landmark Bank for Sav.*, 758 F. Supp. 48, 51 (D. Mass. 1991) ("Allegations in the form of mere conclusions, accusations, or speculation are not sufficient to meet Rule 9(b)'s particularity requirement without supporting facts . . . ."). While Plaintiffs also note that one of the FDA's May 2017 observations about particulate matter purportedly concerned *some* batches Ocular manufactured between February 2016 and May 2017 (Opp. at 14; Compl. ¶¶ 50-51 (Dkt No. 63)), Plaintiffs do not dispute that this observation does not appear in the February 2016 Form 483, and fail even to allege that this observation actually pertains to any batch Ocular manufactured as of the date of the February 2016 Form 483. *See* Compl. ¶ 50 (alleging that Observation 1 concerned less than half of the batches at issue).

2. The cGMP Statements Are Not Misleading By Omission

The Opposition also fails to salvage Plaintiffs' claim that the challenged cGMP statements were misleading due to allegedly incomplete disclosures regarding the Form 483s. Opp. at 14-15. Ocular's disclosures of the Form 483s were far from "summary." Ocular not only disclosed its receipt of the Form 483s, but also provided details about the FDA's observations, including what Plaintiffs refer to as the "bombshell finding" regarding particulate matter in drug batches. Mem. at 9-11 & Exs. A at 85, D at 7, F at 17.

The securities laws do not require Ocular to have disclosed every last detail related to the Form 483s or cast the FDA's observations in a particular negative way. *See Coyne v. Metabolix, Inc.*, 943 F. Supp. 2d 259, 269 (D. Mass. 2013) ("A defendant does not have a duty to cast the descriptions of its business in the most negative light."); *Guerra v. Teradyne Inc.*, No. 01-11789-NG, 2004 WL 1467065, at *10 (D. Mass. Jan. 16, 2004) (no duty to disparage company's own competitive position in market where it has provided accurate data from which analysts and investors can draw their own conclusions); *Johnson v. Pozen Inc.*, No. 1:07CV599, 2009 WL 426235, at *19 (M.D.N.C. Feb. 19, 2009) (no duty to disclose "every detail of [defendant's] FDA correspondence," even where they included safety concerns).[6] Ocular disclosed its receipt of the two Form 483s and disclosed what Plaintiffs contend is the key finding regarding particulate matter. Nothing more was required. *See In re Genzyme*, 2012 WL 1076124, at *10 ("It simply cannot be that every critical comment by a regulatory agency—even about matters as

[6] The cases Plaintiffs cite (Opp. at 15-16) illustrate the types of factual statements that could give rise to a duty to disclose and are readily distinguishable. *Rihn v. Acadia Pharm. Inc.*, No. 15CV00575 BTM (DHB), 2016 WL 5076147, at *6 (S.D. Cal. Sept. 19, 2016) (company failed to disclose that it did not conduct any meaningful assessment of manufacturing and quality assurance systems when it represented that all appropriate steps had been taken to ensure that NDA would be submitted on particular date); *Hill v. State St. Corp.*, No. 09CV12146-NG, 2011 WL 3420439, at *20 (D. Mass. Aug. 3, 2011) (company failed adequately to disclose the company's exposure when it assured investors that debt securities in its investment portfolio were of high quality).

important as good manufacturing practices—has to be seen as material for securities law reporting purposes.").[7]

B. The Challenged November 9, 2016 Earnings Call Statements Are Not Actionable

Plaintiffs concede that one of Dr. Sawhney's statements during the November 9, 2016 earnings call ("We believe we have taken the appropriate steps to address the manufacturing related items raised by the FDA . . . .") is an inactionable statement of opinion and corporate optimism (*see* Mem. at 11-15), as the Opposition focuses solely on Dr. Sawhney's statement that "we've adequately we think addressed the issues that [the FDA] raised" (Opp. at 16-18). In an effort to show that this statement is something other than inactionable puffery and opinion, Plaintiffs characterize it as "Defendants' guarantee" (*id.* at 16) and a "statement assuring adequate resolution" of the FDA observations (*id.* at 18). But Dr. Sawhney's use of "we think" belies any claim that he made a "guarantee" that Ocular had fully addressed the FDA's observations or "assured" investors that Ocular would obtain FDA approval. *See Harrington v. Tetraphase Pharm. Inc.*, Nos. 16-10133-LTS, 16-10577-LTS, 2017 WL 1946305, at *11 (D. Mass. May 9, 2017) ("reasonable investor would understand that" use of "We believe" and "I think" signals "that the statement is an opinion about future potential" (quoting *Cody v.*

[7] Plaintiffs' attempt to distinguish this Court's decision in *Genzyme* is unpersuasive. While Plaintiffs suggest *Genzyme* is "factually distinct" because the case concerned only "general assurances regarding FDA approval" (Opp. at 15 & n.11), Plaintiffs fail to appreciate the key factual distinction: in *Genzyme*, unlike here, *the defendants did not disclose* receipt of a Form 483 for *almost five months*, and then only after the FDA issued a Warning Letter related to those observations. *In re Genzyme*, 2012 WL 1076124, at *3-*4. The Court nonetheless found the inspectional observations in the Form 483 to be "of doubtful materiality" (*id*. at *10) – even though the defendants made certain of the challenged statements about FDA approval after receipt (but before disclosure) of the Form 483. *Id*. at *3. Plainly, if the *undisclosed* Form 483 in *Genzyme* was not material to the challenged statements about FDA approval, it follows that Ocular was under no duty to disclose additional details about the Form 483s here.

Conformis, Inc., 199 F. Supp. 3d 409, 419 (D. Mass. 2016)).[8] Indeed, given the cautions Ocular provided throughout the class period regarding the regulatory approval process (*see* Mem. at 16-17 (collecting cautionary statements)), a reasonable investor would not construe this challenged statement as a "guarantee" of anything. *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1330 (2015) (statement of opinion must be evaluated "in its full context").[9]

Plaintiffs ignore the law by arguing that this statement cannot be puffery because it concerned an allegedly material subject matter. Opp. at 16-17 n.14. The analysis of puffery turns on the language used, not the purported importance of the subject matter. *See In re Cytyc Corp. Sec. Litig.*, No. Civ.A. 02-12399-NMG, 2005 WL 3801468, at *20 (D. Mass. Mar. 2, 2005) (puffery analysis assesses whether challenged statement is "specific, definite or concrete").[10] Dr. Sawhney's challenged statement here—"we've adequately we think addressed the issues that they've raised" (Compl. ¶ 71)—is a classic example of non-actionable corporate

[8] Tellingly, elsewhere in their puffery argument, Plaintiffs simply omit the qualifying "we think" when they describe this challenged statement: "Here, as explained above, [Dr.] Sawhney's statement that Ocular had adequately addressed the FDA's observed deficiencies were [sic] highly material." Opp. at 17 n.14. This bald attempt to rewrite Dr. Sawhney's qualified opinion as a declarative statement only further highlights the weakness of Plaintiffs' claim.

[9] Plaintiffs' citation to *In re Transkaryotic Therapies, Inc. Sec. Litig.*, (Opp. at 16-17) is of no assistance. There, the court found the complaint sufficiently pleaded that the company made a material omission in withholding the FDA's opinion that clinical studies did not show the efficacy of the company's product and instead effectively guaranteed FDA approval. 319 F. Supp. 2d 152, 156, 159-60 (D. Mass. 2004). The FDA's Complete Review Letter explicitly stated that clinical studies were "uninterpretable," "failed to demonstrate efficacy" of the company's drug product, and that further analyses of existing data could not support approval, all of which directly contradicted the company's disclosure that the FDA requested further explanation and data. Here, in contrast, Ocular disclosed the FDA's issuance of the Form 483 and made no explicit or implicit guarantee of FDA approval.

[10] Plaintiffs' cases (Opp. at 16-17 n.14) are readily distinguishable, as the courts in those cases found that more specific statements that either directly or implicitly represented facts about current operations were not mere statements of corporate optimism. *See Brumbaugh v. Wave Sys. Corp.*, 416 F. Supp. 2d 239, 250-51 (D. Mass. 2006) (announcement of agreement was not so vague to be considered a statement of corporate optimism, especially in light of recent pronouncements of strategic and profitable alliances); *In re Smith & Wesson Holding Corp. Sec. Litig.*, 604 F. Supp. 2d 332, 342 (D. Mass. 2009) (statements regarding the strength of past demand and "backlog" orders sufficiently "definite and important to a potential investor"); *In re Boston Sci. Corp. Sec. Litig.*, No. 10-10593-DPW, 2011 WL 4381889, at *12 (D. Mass. Sept. 19, 2011) (optimistic statements about strength of sales force actionable where plaintiff pleaded defendants were aware that the termination of sales representatives may impact the company's revenues), *aff'd*, 686 F.3d 21 (1st Cir. 2012).

puffery. *See Corban v. Sarepta Therapeutics, Inc.*, No. 14-cv-10201-IT, 2015 WL 1505693, at *9 (D. Mass. Mar. 31, 2015) (statement, "the FDA's feedback was the 'type of information that every company hopes for which is an encouraging sign from the FDA that a mid-stage trial, a phase II study is strong in enough to consider for an NDA filing'" was not "not materially misleading merely because Plaintiffs seem to take issue with the general rosy picture that defendants attempted to paint" (alteration incorporated) (internal quotation marks omitted)).[11]

The Opposition's effort to establish that Dr. Sawhney's statement is not a protected statement of opinion fares no better. Contrary to Plaintiffs' argument (Opp. at 17-18), the only reasonable inference the Court can draw from Plaintiffs' pleading is that the challenged statement did "fairly align[]" with the information in Ocular's possession at the time of the statement. *Omnicare*, 135 S. Ct. at 1329. Plaintiffs' argument here rests entirely on Ocular's apparent inability to resolve the FDA's observations in the five months between the February 2016 Form 483 and the July 2016 Complete Response Letter. Opp. at 18. But Dr. Sawhney made the statement at issue *four months later*, after Ocular received a favorable letter from the FDA (which Ocular described in its August 9, 2016 Form 8-K) regarding the corrective actions that the Company had proposed in response to the February 2016 Form 483.[12] Plaintiffs are unable to offer any contemporaneous facts showing that the challenged statement of opinion—

[11] Although the Opposition cites *W. Virginia Pipe Trades Health & Welfare Fund v. Medtronic, Inc.* for the proposition that courts may find vague statements to be actionable when made in response to a specific inquiry (Opp. at 16-17 n.14), that decision concluded that nothing in the context of the statements at issue pushed them "beyond the realm of immaterial puffery." 57 F. Supp. 3d 950, 970 (D. Minn. 2014). Dr. Sawhney's qualified and cautiously optimistic response is similarly situated. While Plaintiffs also cite *Oran v. Stafford* for the proposition that declines in Ocular's stock price show the materiality of the subject matter (Opp. 16 n.12), that decision confirms that "share price activity . . . . does not end [the] inquiry," noting that "[e]ven non-disclosure of material information will not give rise to liability . . . unless [there was] an affirmative duty to disclose." 226 F.3d 275, 285 (3d Cir. 2000). There, as here (Mem. at 9-11), there was no duty to make additional disclosures. *Oran*, 226 F.3d at 285-86.

[12] Even if, as Plaintiffs suggest, the FDA's August 2016 letter was merely an "approval of Ocular's remediation plan" (Opp. at 18 n.15), this FDA response would still support the opinions Dr. Sawhney expressed during the November 9, 2016 earning call. At the very least, this encouraging FDA response undercuts Plaintiffs' suggestion that the information available to Ocular did not "fairly align" with Ocular's expressions of optimism.

"we've adequately we think addressed the issues that [the FDA] raised"—did not "fairly align" with the information available to Ocular as of November 9, 2016.

C. The Challenged May 5, 2017 Earnings Call Statements Are Not Actionable

Defendants' opening brief demonstrated that the challenged statements from the May 5, 2017 earnings call either are inactionable forward-looking statements, or statements of corporate optimism or opinion that similarly are not actionable. Mem. at 15-20. In response, Plaintiffs challenge only those statements where Defendants indicated that Ocular expected to be able to resolve the FDA's observations "in a timely manner." Opp. at 18-20. The Opposition fails to establish that these statements are actionable.

Plaintiffs do not contest the forward-looking nature of Defendants' statements that Ocular expected to be able to resolve the May 2017 FDA observations "in a timely manner." Instead, Plaintiffs attempt to avoid the PSLRA's safe harbor by claiming that these forward-looking statements were not accompanied by "meaningful" cautionary language. *Id.* Ocular specifically cautioned that "[a]dequate resolution of the outstanding Form 483 inspectional observations . . . . is a prerequisite to the approval of the NDA for Dextenza." Mem. Ex. F at 17. Ocular further warned that "[i]f we are unable to resolve these inspectional observations in a timely manner, potential approval of the NDA would be delayed or prevented." *Id.* at 34. These disclosures, which Ocular made on the same day as the challenged statements, go far beyond the "boilerplate" warnings found insufficient in other cases. *See, e.g., In re Ibis Tech. Sec. Litig.*, 422 F. Supp. 2d 294, 311 (D. Mass. 2006) ("it is not necessary for a defendant to describe the particular factor that ultimately causes the forward-looking statement to not come true, as long as the warnings accompanying the statement mention important factors that could cause actual

results to differ materially from those in the forward-looking statement" (internal quotation marks omitted)).[13]

Plaintiffs also seek to avoid the safe harbor by arguing that it does not apply to omissions. Opp. at 20. This is a red herring—Defendants have not argued that any alleged omission is rendered inactionable by the safe harbor. In any event, the claim that the PSLRA safe harbor does not apply to omissions has been rejected by over a decade of case law. *See Grobler v. Neovasc Inc.*, No. 16-11038-RGS, 2016 WL 6897760, at *2 (D. Mass. Nov. 22, 2016) ("Under the safe harbor provision, a party is immunized for otherwise materially misleading statements or omissions . . . ."); *Meyer v. Biopure Corp.*, 221 F. Supp. 2d 195, 203 (D. Mass. 2002) (similar); *see also* 15 U.S.C. § 78u-5(c)(1)(a).

Additionally, statements that Ocular expected to be able to resolve the FDA's observations "in a timely manner" are classic expressions of corporate optimism or opinion that are not actionable. Mem. at 18-19; *see* section I.B *supra*. Plaintiffs respond that these statements should give rise to a claim because they "conceal[] the conflicting known fact that the same deficiencies dating back to February 2016 were still present" and carried over to the May 2017 Form 483. Opp. at 18-19. But as shown above, Plaintiffs' allegations fail to establish any overlap between the February 2016 and May 2017 FDA observations, including with respect to

[13] Plaintiffs' citation to an out of-circuit case, *Washtenaw Cty. Employees Ret. Sys. v. Celera Corp.*, No. 5:10-cv-02604, 2012 WL 3835078 (N.D. Cal. Sept. 4, 2012) is inapposite, as that case did not address the sufficiency of the cautionary statements issued by the defendant, finding instead that "[t]he safe harbor cannot protect cautionary statements made with superior knowledge that some of the perils identified have in fact been realized." *Id*. at *4. Here, Plaintiffs have not alleged sufficient facts to support an inference that Defendants had "superior knowledge" of risks that had already materialized. *See* section II.A *infra.*

the particulate issue that the FDA raised for the first time in the May 2017 Form 483. *See* section I.A *supra.*[14]

Plaintiffs otherwise argue that challenged statements about Ocular's expectations were false because they purportedly "omitted the most critical problems identified in th[e] Form 483." Opp. at 8; *see id.* at 19. But the allegations in the Complaint and the documents incorporated therein do not support this characterization. As discussed, far from downplaying the significance of the May 2017 Form 483, Ocular disclosed that it had received the May 2017 Form 483, the substance of the FDA's observations, and the particulate issue that Plaintiffs identify as the supposed "bombshell finding." Mem. at 19-20; s*ee* section I.A *supra*. Ocular has no duty to disparage itself, adopt a particular characterization of the FDA's observations, or disclose every particular detail regarding the May 2017 Form 483 or the Company's discussions with the FDA. *See Coyne*, 943 F. Supp. 2d at 269.

D. The Allegations From Plaintiffs' Sole "Confidential Witness" Are Not Reliable And Do Not Render Any Challenged Statement False

In their Opposition, Plaintiffs concede that their sole confidential witness ("CW") has no knowledge relevant to the challenged March 2016 cGMP statement or the challenged November 9, 2016 and May 5, 2017 earnings call statements (Opp. at 29-30) – a necessary concession given the CW's limited alleged dates of employment at Ocular. *See* Mem. at 21. While Plaintiffs thus offer their CW for the sole purpose of supporting their claims regarding the March 2017 cGMP statement, the Opposition fails to demonstrate that the Court should credit these allegations, even for this limited purpose.

[14] Plaintiffs' citation to *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110 (C.D. Cal. 2005) (Opp. at 18-19) is unavailing. In that case, the company failed to disclose the receipt of the Form 483, any of the objectional conditions noted in the 483, or the company's response. 388 F. Supp. 2d at 1119, 1129. By contrast, Ocular not only disclosed the receipt of the 483, but it also disclosed the particulate issue and the risks of delay to FDA approval posed by the Form 483.

As an initial matter, Plaintiffs cannot satisfy their pleading burden simply by identifying the CW's alleged dates of employment and position as a Regulatory Affairs Project Manager. *See* Opp. at 29. Without additional allegations describing the CW's job duties – and Plaintiffs offer no allegations that the CW had any role regarding manufacturing or cGMP compliance, or even a role regarding DEXTENZA – the Complaint fails to provide "sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *In re Cabletron Sys., Inc.*, 311 F.3d 11, 29 (1st Cir. 2002); *see also Phillips v. Triad Guar., Inc.*, No. 1:09CV71, 2015 WL 1457980, at *5 (M.D.N.C. Mar. 30, 2015); *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 595 (S.D.N.Y. 2011).[15]

In any event, the Opposition fails to establish that the CW has knowledge relevant to the challenged March 2017 cGMP statement. Plaintiffs do not suggest that the CW has knowledge of cGMP requirements, Ocular's manufacturing practices, or Ocular's cGMP compliance (and the Complaint's sparse CW allegations would not permit such an argument anyway). Rather, the CW's sole purported contribution to the case is his claim of Mr. Ankerud's alleged "admission" that Ocular would be including batch records in its NDA resubmission that would not meet FDA standards. Opp. at 28.[16] But Plaintiffs fail to explain how this alleged conversation is at all relevant to cGMP compliance. *See* Mem. at 22. Rather than identify some cGMP requirement

[15] Plaintiffs take issue with Defendants' citations to out-of-circuit authority regarding the level of detail required to plead confidential witness allegations. Opp. at 28. But Plaintiffs cannot seriously dispute that, at a minimum, a well-pleaded complaint challenging statements about a certain drug product must allege a basis to support the conclusion that the CW has actual first-hand knowledge of the product at issue. This is a significant omission here, given that the CW could have worked on Ocular's ReSure product or other products in Ocular's pipeline.

[16] In a transparent attempt to strengthen their claim, Plaintiffs mischaracterize their own CW's alleged statement *twice* in their Opposition. While the Complaint alleges a conversation between the CW and Mr. Ankerud about the sufficiency of the batch records in the NDA resubmission (Compl. ¶ 46), Plaintiffs repeatedly omit "batch records" from their characterization of the CW allegations in order to suggest that the alleged statement has a broader and more general applicability. *See* Opp. at 2 (CW "revealed that Ankerud admitted that Ocular's NDA resubmission would not meet FDA standards."), 29 (CW had personal knowledge of "Ankerud's highly damaging admission that 'the NDA resubmission that would not meet FDA standards.'").

related to batch records, Plaintiffs instead just (1) repeat their allegations regarding the Form 483s and (2) note that cGMP compliance is required for NDA approval (Opp. at 30) – without explaining how batch records pertain to either issue. Indeed, while Plaintiffs allege that the batch records in the NDA resubmission would not meet "FDA standards," they do not even allege that these unspecified "FDA standards" related to cGMP issues. In sum, because Plaintiffs do not allege any link between batch records and cGMP compliance, the CW's allegations have no bearing on the challenged March 2017 cGMP statement.[17]

II. PLAINTIFFS' ALLEGATIONS FAIL TO RAISE A STRONG INFERENCE OF SCIENTER

A. Plaintiffs Have Not Alleged Particular Facts Indicating That Defendants Knew Or Were Reckless In Not Knowing Any Statement Was False

Even if the Complaint had adequately alleged that the Defendants made false or misleading statements regarding cGMP compliance or the Form 483s —which it has not— Plaintiffs' claims still fail because Plaintiffs' scienter theory does not approach the realm of "cogent and compelling." Plaintiffs principally argue that Dr. Sawhney and Mr. Ankerud knew about the observations in the Form 483s, but nevertheless continued to express optimism about the prospects for FDA approval. Opp. at 22-23. But the Complaint offers no basis to conclude that the Defendants knew that Ocular would not be able to address the FDA's observations in a timely manner.

Plaintiffs' scienter allegations amount to little more than a rehash of their falsity allegations. *See* Opp. at 22-27. Thus, these allegations fail for the same reasons as the falsity

[17] The Opposition also reveals that Plaintiffs' argument suffers from a temporal flaw. Given that the CW is describing a purported conversation about Ocular's NDA resubmission (Opp. at 28), this conversation necessarily described an alleged state of affairs as of January 2017, the date of the NDA resubmission (Compl. ¶ 46). Ocular made the challenged March 2017 cGMP statement two months later. While Plaintiffs thus seek to rely on this alleged statement about batch records as of January 2017 to support their claims about the March 2017 cGMP statement, they cannot do so absent an allegation (from the CW or otherwise) that any purported deficiency with Ocular's batch records persisted through March 2017. There is no such allegation.

allegations, namely the absence of any well-pleaded facts reliably showing that, at the time of the challenged statements, Ocular was not cGMP compliant and was doomed to fail in its efforts to obtain FDA approval. *See* section I.A *supra*; *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1232 (S.D. Cal. 2001) (absent adequately pleaded false statement, scienter determination "entails the illogical inquiry into whether the defendant intended to deceive when, in fact, there was no deception"). Ultimately, Plaintiffs cannot avoid that the Complaint fails to offer any communication, meeting, report, reliable witness, or other evidence that Defendants knew or were reckless in not knowing that Ocular would not be able to overcome the FDA's inspectional observations in a timely manner. *See* Mem. at 24-27.

The Opposition devotes three pages (Opp. at 22-24) to demonstrating that Dr. Sawhney and Mr. Ankerud knew about the observations in the Form 483s and their significance.[18] But to allege scienter here, Plaintiffs need to plead more than Defendants' knowledge of the FDA's observations. *See In re Genzyme*, 2012 WL 1076124, at *10 ("Given the FDA's own warnings and enforcement policies surrounding its issuance, one can safely conclude that the immateriality [of] the Form 483 negates any inference of scienter."). Rather, they also need to demonstrate through well-pleaded allegations that Dr. Sawhney and Mr. Ankerud knew that the challenged statements about Ocular's progress in addressing the Form 483s were false when the Defendants made them. *See In re Boston Sci. Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir. 2012) (satisfying pleading standard typically requires "clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so").

[18] *See, e.g.*, Opp. at 22 (seeking to draw significance from allegation that Dr. Sawhney and Mr. Ankerud "personally received" the Form 483s), 23 (noting that the Form 483s "were directed and sent to Sawhney").

There are no such well-pleaded allegations here. The Complaint offers no internal documents, communications or confidential witness allegations suggesting that the Defendants knew Ocular would not be able to resolve the FDA's observations in a timely manner. Plaintiffs seek to remedy this deficiency by offering their own characterizations of the FDA's inspectional observations: according to Plaintiffs, those observations required a "massive overhaul" of Ocular's operations (Opp. at 2), "significant changes … at great expense" (*id.* at 17), and would require a "tremendous undertaking" (*id.* at 22). But Plaintiffs offer no well-pleaded support (*e.g.*, contemporaneous documents or witnesses) for these characterizations. Plaintiffs' own speculation about the relative significance of the FDA's observations is no substitute for the well-pleaded facts required to plead scienter. *See Suna v. Bailey Corp.*, 107 F.3d 64, 68 (1st Cir. 1997) (plaintiffs cannot base scienter and "claims of fraud on speculation and conclusory allegations"); *Fitzer v. Sec. Dynamics Techs., Inc.*, 119 F. Supp. 2d 12, 25 (D. Mass. 2000) (declining to draw inference of scienter based on speculation). In any event, even if the FDA's observations did require a "tremendous undertaking" to resolve, Plaintiffs fail to allege facts demonstrating that Dr. Sawhney and Mr. Ankerud did not believe that Ocular was prepared to take on this level of effort in order to address the FDA's observations.[19]

Unable to offer any well-pleaded allegations that Dr. Sawhney or Mr. Ankerud knew a fact contrary to a challenged statement, Plaintiffs seek to impute knowledge to these individuals based on the "core operations" doctrine. But as noted in Defendants' opening brief, this theory is a very narrow exception to the general prohibition on pleading scienter by status. Mem. at 27; *see In re A123 Sys., Inc. Sec. Litig.*, 930 F. Supp. 2d 278, 285-86 (D. Mass. 2013). The truism

[19] As explained above, *see* Section I.D *supra*, the allegations of Plaintiffs' sole confidential witness are unreliable, and Plaintiffs have offered no connection between those allegations about batch records and the FDA's decision not to approve Ocular's NDA.

that Dr. Sawhney and Mr. Ankerud had an incentive to pay close attention to the Company's key operations cannot substitute for specific factual allegations that they knew that Ocular would be unable to overcome the FDA's observations in a timely manner. *See In re Psychemedics Corp. Sec. Litig.*, No. 17-10186-RGS, 2017 WL 5159212, at *6 (D. Mass. Nov. 7, 2017) (disregarding "core operations" theory because it "stands on naked, unadorned by any other piece of evidence purporting to establish the essential 'plus' factor," *i.e.*, particularized facts).

B. A "Holistic" View Of The Complaint's Allegations Fail To Raise A Strong Inference Of Scienter

Plaintiffs fare no better with their proposed "holistic approach" to scienter. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007) ("The inquiry ... is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard."). In this regard, Plaintiffs argue principally that the presence of an SEC investigation is a "piece" of the holistic "puzzle" that supports an inference of scienter. Opp. at 26-27. Of course, it is well-established that the existence of an SEC investigation, standing alone, does not support an inference of scienter. *See Godinez v. Alere Inc.*, 272 F. Supp. 3d 201, 219 (D. Mass. 2017) ("the existence of a subpoena does not, without more, give rise to a strong inference of scienter on the part of senior management."); *In re Hutchinson Tech., Inc. Sec. Litig.*, 536 F.3d 952, 962 (8th Cir. 2008) ("The mere existence of an SEC investigation does not suggest that any of the allegedly false statements were actually false . . . [or] material[,] nor does it add an inference of scienter."); *In re Gentiva Sec. Litig.*, 932 F. Supp. 2d 352, 380 (E.D.N.Y. 2013) ("the mere commencement and pendency of" SEC and other regulatory "investigations cannot support a strong inference of scienter, because 'the fact that a regulator is fulfilling this role cannot be sufficient to allege

scienter'" (quoting *In re Manulife Fin. Corp. Sec. Litig.*, 276 F.R.D. 87, 102 (S.D.N.Y. 2011)).[20] Taken together with all of the other allegations (or the absence thereof) bearing on the scienter inquiry here, including the absence of any insider trading or other motive allegations, the lack of relevant and reliable CW allegations, Ocular's prompt disclosure of both Form 483s, and Dr. Sawhney's *purchases* of Ocular stock during the class period, Plaintiffs fall short of the strong inference of scienter necessary to support their claim. Mem. at 27-28; *see also In re Genzyme*, 2012 WL 1076124, at *12 (timely disclosures "seriously undermine an inference of intent to deceive."). As in *Genzyme*, the more reasonable inference is that Ocular "was attempting to develop a [drug] that the defendants considered to be beneficial and that they believed was progressing, if fitfully at times, towards FDA approval … and that they reasonably did not expect that the setbacks the company experienced … would have a significant impact on the ultimate approval so as to require more disclosure than there had been." *Id.*[21]

III. PLAINTIFFS CONCEDE THAT THEY FAIL TO STATE A CLAIM AGAINST DEFENDANTS HURLEY AND MIGAUSKY

As set forth in Defendants' opening brief (Mem. at 23-24), Plaintiffs' claims against Messrs. Hurley and Migausky fail for the additional reason that Plaintiffs seek to hold them liable for statements made by others, without alleging that either defendant had any control over the challenged statements. Plaintiffs do not contest Defendants' motion as it relates to Messrs. Hurley and Migausky. Opp. at 1 n.2. Thus, the Court should dismiss all claims against Messrs. Hurley and Migausky with prejudice.

[20] The very case Plaintiffs cite for this proposition clarifies that a "governmental investigation . . . is insufficient in and of itself" to establish a strong inference of scienter. *Washtenaw Cty. Emps. Ret. Sys. v. Avid Tech., Inc.*, 28 F. Supp. 3d 93, 114 (D. Mass. 2014).

[21] The Complaint does not plead control person liability. Opp. at 30. Having failed to plead a primary violation, Plaintiffs' Section 20(a) "control person" claim also fails. *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 67 (1st Cir. 2008) ("The plain terms of section 20(a) indicate that it only creates liability derivative of an underlying securities violation."); *In re First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145, 165 (D. Mass. 2009) (dismissing control-person claim for same reason).

IV. PLAINTIFFS SHOULD NOT BE GRANTED FURTHER LEAVE TO AMEND THE COMPLAINT

Dismissal here should be with prejudice. Although Plaintiffs have requested leave to amend in the event the Court grants Defendants' motion (Opp. at 30 n.21), a "district court enjoys significant latitude in deciding whether to grant leave," and grounds to deny leave include "'undue delay . . . [and] repeated failure to cure deficiencies by amendments previously allowed . . . .'" *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 55-56 (1st Cir. 2008) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)). Plaintiffs may not "wait in the wings" until a court finds their complaint insufficient. *Id.* at 57. Here, Plaintiffs have already amended their pleadings. *See* Dkt. No. 63. Plaintiffs could have sought leave to replead after being served with Defendants' motion to dismiss, but chose to defend their Complaint instead. Moreover, Plaintiffs fail to provide the Court "with the reasons supporting their request and with the substance of possible amendments." *Silverstrand Invs. v. AMAG Pharm., Inc.*, 707 F.3d 95, 107 (1st Cir. 2013). Plaintiffs "should not seriously expect to obtain a remedy without doing the necessary leg work first." *Id.*

V. CONCLUSION

For all the foregoing reasons, and the reasons set forth in Defendants' opening memorandum, the Court should dismiss the Consolidated Amended Class Action Complaint in its entirety, with prejudice.

Respectfully Submitted,

Dated: October 4, 2018

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was served on the participants of the ECF system in the above-captioned matter on October 4, 2018.

Dated: October 4, 2018

/s/ Peter J. Kolovos
Peter J. Kolovos